



P2.365: Patient-Centric Phase II Trial (CTONG2203) in ALK-Positive NSCLC: Baseline Characteristics and Adapted Follow-Up

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INTRODUCTION

- Lorlatinib demonstrated substantial systemic and intracranial efficacy in the global CROWN study, achieving a 7-year PFS rate of 55%.¹ Consistent benefit has been reported in Asian patients, supporting further evaluation in broader Chinese populations in real-world settings.^{2,3} Moreover, frequent conventional on-site follow-up may add to patient burden and lead to premature withdrawal.
- CTONG2203 evaluates first-line lorlatinib in CROWN-matched and expanded-eligibility patients, alongside a real-world observational cohort receiving physician's choice of ALK TKI, and explores patient-centric adaptations to long-term follow-up.^{3,4}

METHODS

- The CTONG2203 trial is a patient-centric, prospective, 3-cohort, open-label, multicenter, phase II study (NCT06092086). All newly diagnosed patients with ALK-positive NSCLC were consecutively enrolled within the same cross-sectional enrollment window. The study assesses lorlatinib efficacy, safety and resistance in a broader population and characterizes real-world treatment patterns and survival (Figure 1).
- The primary endpoint is PFS (rwPFS for the RO cohort); secondary and exploratory endpoints for treatment intervention cohorts include intracranial outcomes (IC-TTP, IC-ORR), ORR, OS, safety, PRO, and lorlatinib resistance/post-line treatment strategies.
- A patient-centric flexible follow-up model was developed based on patient feedback, with ethics approval and data validation (Figure 2).

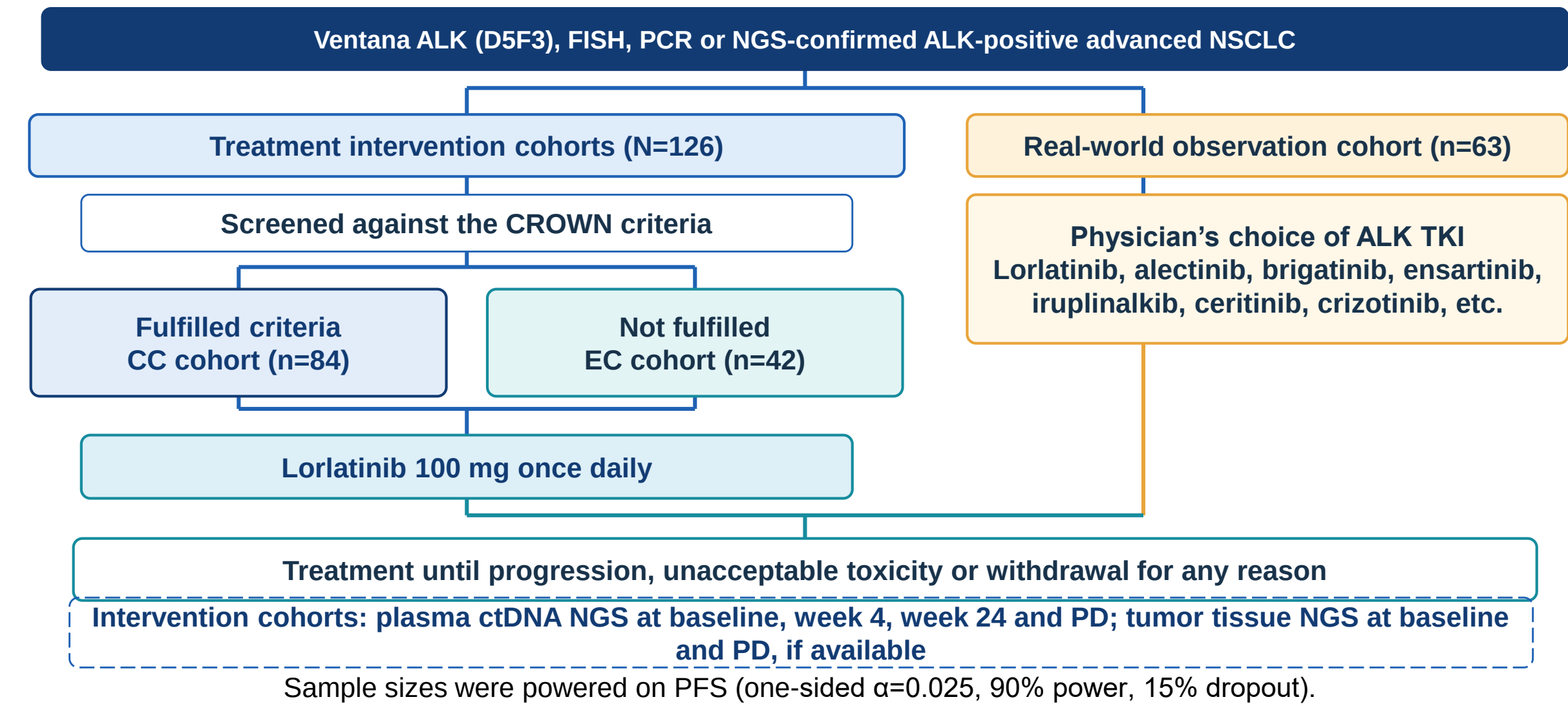


Figure 1. CTONG2203 study design.

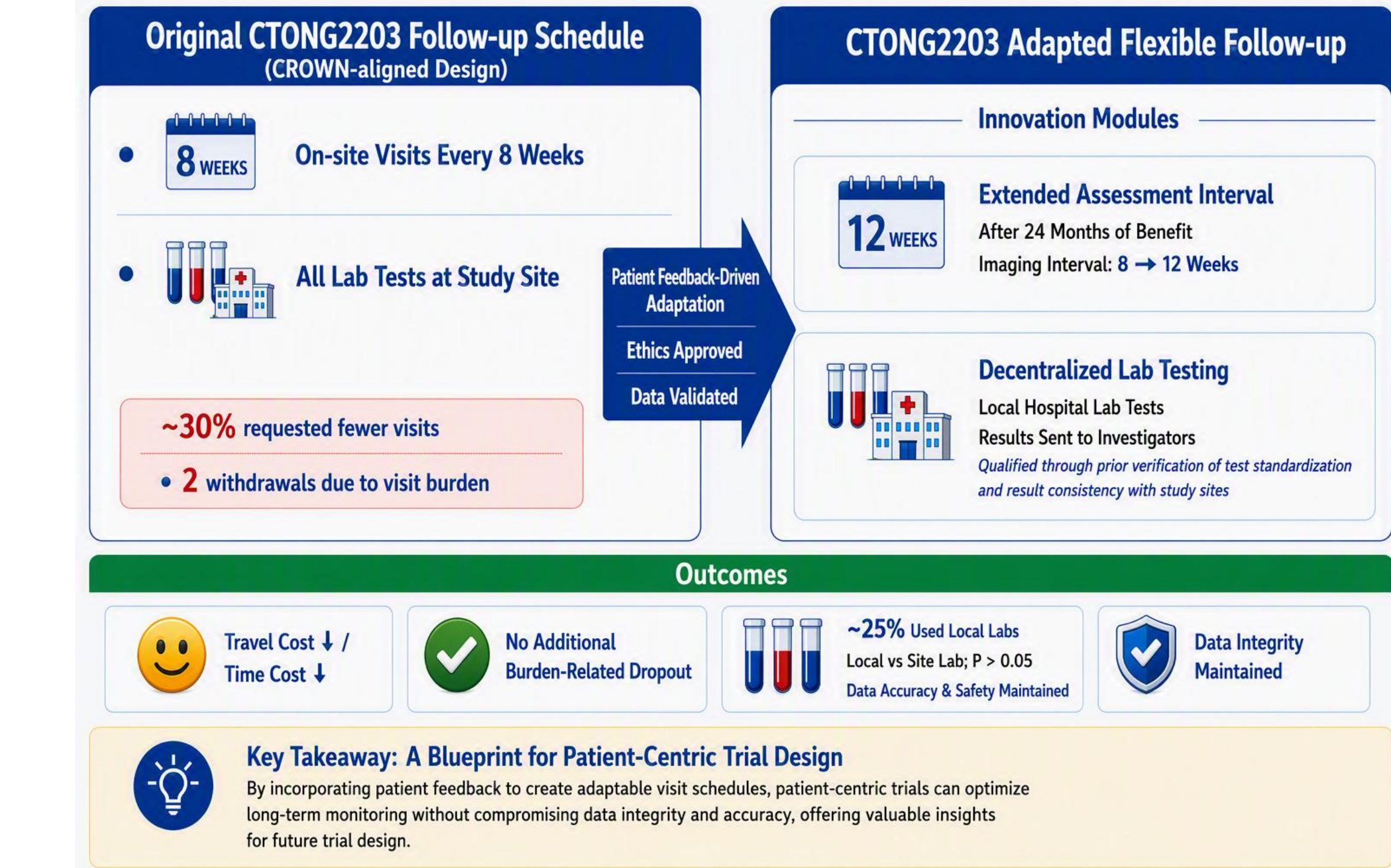


Figure 2. Patient-centric adapted follow-up and outcomes.

RESULTS

Baseline characteristics

- Between August 2023 and June 2025, 189 patients were enrolled across 9 centers (CC, n=85; EC, n=41; RO, n=63). Most patients had stage IV adenocarcinoma, and 29.4%–34.9% had baseline brain metastases. In the RO cohort, first-line ALK-TKI was third-generation in 57.1% and second-generation in 42.9% of patients. (Table 1)
- All patients received at least one dose of protocol-assigned treatment, and as of the data cutoff on 20 June 2026, 142 patients (75.1%) remained on study.

Characteristic, n (%)	CC (n=85)	EC (n=41)	RO (n=63)
Age, median, years	55	58	50
Sex			
Male	39 (45.9)	23 (56.1)	24 (38.1)
Female	46 (54.1)	18 (43.9)	39 (61.9)
ECOG PS			
0–1	85 (100.0)	36 (87.8)	61 (96.8)
2–3	0 (0.0)	5 (12.2)	2 (3.2)
Smoking status			
Never	64 (75.3)	28 (68.3)	56 (88.9)
Ever	21 (24.7)	13 (31.7)	7 (11.1)
Clinical stage			
III	9 (10.6)	3 (7.3)	8 (12.7)
IV	76 (89.4)	38 (92.7)	55 (87.3)
Histology			
Adenocarcinoma	83 (97.6)	41 (100.0)	59 (93.6)
Squamous cell carcinoma	1 (1.2)	0 (0.0)	1 (1.6)
NSCLC, NOS	1 (1.2)	0 (0.0)	1 (1.6)
Other	0 (0.0)	0 (0.0)	2 (3.2)*
Baseline brain metastases			
Yes	25 (29.4)	14 (34.1)	22 (34.9)
No	60 (70.6)	27 (65.9)	41 (65.1)
First-line ALK-TKI†			
Lorlatinib	85 (100.0)	41 (100.0)	36 (57.1)
Second-generation ALK-TKI	0 (0.0)	0 (0.0)	27 (42.9)

Table 1. Baseline characteristics.

*one sarcomatoid carcinoma and one adenosquamous carcinoma.
† four patients switched agents during treatment without progression.

Tumor response

- ORR was 94.1% in CC, 92.7% in EC and 76.2% in RO, driven predominantly by partial responses;
- DCR remained high throughout at 98.8%, 95.1% and 96.8% for CC, EC and RO, respectively (Table 2).

	CC (n=85)	EC (n=41)	RO (n=63)
Type of response, n (%)			
CR	1 (1.2)	2 (4.9)	4 (6.3)
PR	79 (92.9)	36 (87.8)	44 (69.8)
SD	4 (4.7)	1 (2.4)	13 (20.6)
PD	1 (1.2)	1 (2.4)	2 (3.2)
NE	0	1 (2.4)*	0
ORR [95% CI]	80 (94.1) [86.9–97.4]	38 (92.7) [80.6–97.5]	48 (76.2) [64.4–85.0]
DCR [95% CI]	84 (98.8) [93.6–99.8]	39 (95.1) [83.9–98.7]	61 (96.8) [89.1–99.1]

Table 2. Summary of tumor response by cohort.

*One EC patient received study treatment for 10 days and discontinued without undergoing any efficacy assessment.

Progression-free survival

- At the data cutoff of 20 June 2026, with a median follow-up of 18.5 months, median PFS was not reached in any cohort. The 1-year PFS rates were 88.2%, 90.2% and 82.5% in the CC, EC and RO cohorts, respectively (Figure 3).
- PFS benefit was observed irrespective of baseline BM status, with 1-year PFS rates of 90.0% (non-BM) and 84.0% (BM) in the CC cohort, as well as 92.6% (non-BM) and 85.7% (BM) in the EC cohort (Figures 4 and 5).

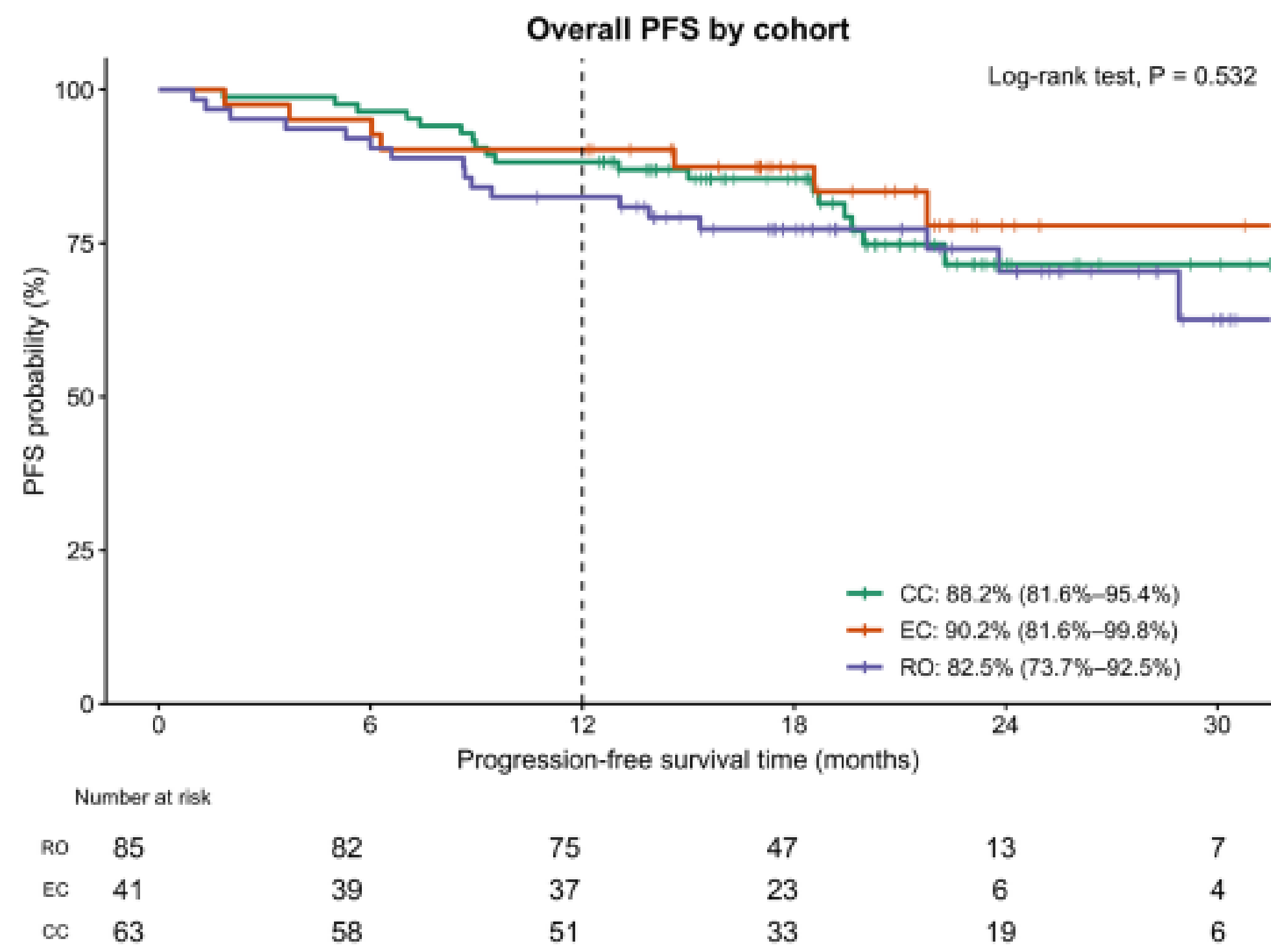


Figure 3. Kaplan–Meier analysis of PFS by cohort.

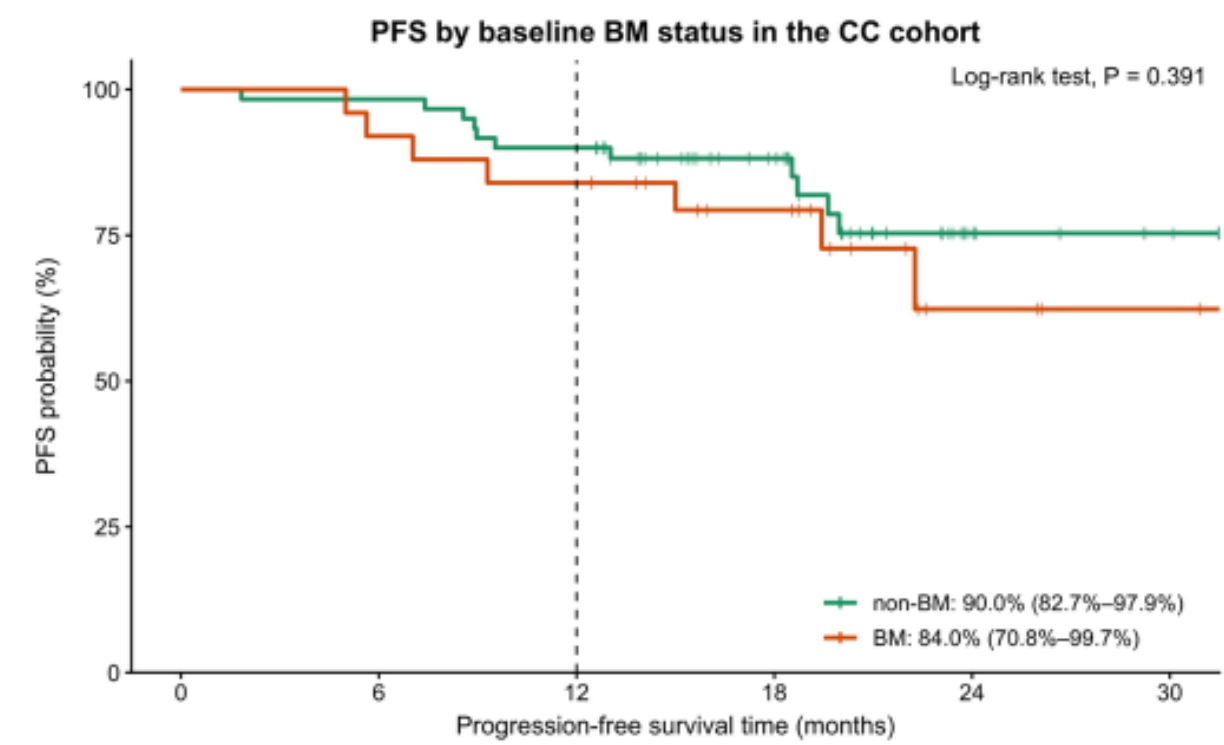


Figure 4. Kaplan–Meier analysis of PFS in the CC cohort by baseline brain metastasis status.

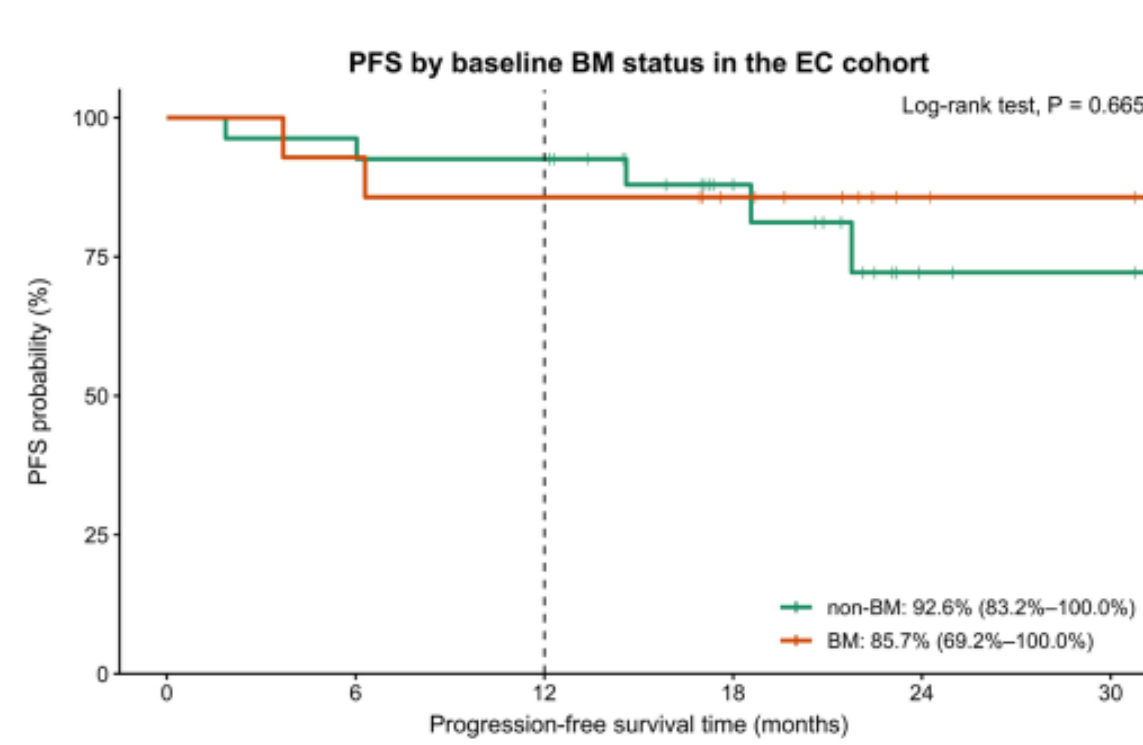


Figure 5. Kaplan–Meier analysis of PFS in the EC cohort by baseline brain metastasis status.

CC, CROWN criteria cohort; EC, expanded eligibility criteria cohort; RO, real-world observation cohort; NOS, not otherwise specified; aNSCLC, advanced non-small cell lung cancer; PFS, progression-free survival; BM, brain metastases.

CONCLUSIONS

- To our knowledge, CTONG2203 is the first patient-centric study in ALK-positive NSCLC that enrolls a broader population across CROWN-matched, expanded-eligibility and real-world cohorts, bridging the limited CROWN Chinese data gap while expanding real-world evidence for ALK-TKIs.
- Response rates were high across three cohorts (ORR 94.1%, 92.7% and 76.2% in CC, EC and RO), with encouraging 1-year PFS rates (88.2%, 90.2% and 82.5%), and the PFS benefit was observed irrespective of baseline BM status. These preliminary data suggest consistent antitumor activity of lorlatinib in a broader Chinese patients. Longer follow-up is warranted.
- By integrating methodological quality with real-world representativeness, CTONG2203 provides a pragmatic trial paradigm. The patient-centric follow-up schedule mitigated visit burden without compromising protocol adherence, offering a feasible blueprint for future lung cancer trials.

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